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REMARKS

Claim Status

Claims 1 - 52 are pending in the present application.

Independent claims 1 and 40 have been amended to include the features of a biosensor adapted to detect a target biological analyte present at a low concentration in bodily waste.

Support for this amendment can be found at page 12, line 33 of the application.

Rejection Under 35 USC §102

Claims 1-11, 15-35 and 40-48 have been rejected under 35 U.S.C. 102(b) as being aniticpated by US 5,468,236 to Everhart et al.

Applicants respectfully traverse the rejection in view of the following remarks.

At the outset, Applicants submit that independent claim 1 is directed to a disposable article to be fitted to a wearer comprising a biosensor including at least one bio-recognition element, the biosensor being adapted to detect a target biological analyte present at a low concentration in bodily waste or on the wearer's skin and that independent claim 40 is directed to disposable absorbent article to be fitted to a wearer comprising a topsheet, a backsheet joined with the topsheet, an absorbent core disposed between the topsheet and the backsheet and a biosensor disposed on the disposable article, the biosensor including at least one bio-recognition element wherein the biosensor is adapted to detect a target biological analyte present at a low concentration in bodily waste. (Emphasis added).

Applicants remind that Office that the present application discloses that:

"[a]s used herein, the term "biosensor" is defined as a component comprising one or more biologically reactive means being adapted to detect one or more target pathogenic microorganisms or related biomolecules (e.g., an enzyme sensor, organella sensor, tissue sensor, microorganism sensor, immunosensor or electrochemical sensor), additionally having the capability to provide a signal of said detection to the wearer, caretaker, or an actuator. The term "biologically reactive" is defined as having the capability to selectively interact with, and preferably bind, target pathogenic microorganisms and/or related biomolecules as described herein. Generally, biosensors function by providing a means of

Page 9 of 12

specifically binding, and therefore detecting, a target biologically active analyte. In this way, the biosensor is highly selective, even when presented with a mixture of many chemical and biological entities, such as feces. Chemical sensors, on the other hand, which rely on chemically reactive means, generally do not have either the high selectivity or the amplification properties of biosensors and, therefore, are not well suited to detect biologically reactive analytes, especially when they are present in low concentrations and/or in a complex media such as bodily waste. Often the target biological analyte is a minor component of a complex mixture comprising a multiplicity of biological and other components. Thus, in many biosensor applications, detection of target analytes to the parts-perbillion, parts-per-trillion, or even lower levels is necessary. Accordingly, discrimination ratios of about 10⁷-10⁸ or greater may be required for the biosensor to recognize the target biological analyte in a complex mixture." (See page 12, lines 20-33 and page 13, lines 1-5).

The present application also discloses that:

"The biosensor of the present invention comprises a bio-recognition element, or molecular recognition element, that provides the highly specific binding or detection selectivity for a particular analyte." (See page 13, lines 6-8)

It is well-settled that in order to anticipate a claim, the reference must teach each and every element of the claim. MPEP §2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants submit that contrary to the Office Action assertion, Everhart et al. '236 does not teach or suggest a biosensor including at least one bio-recognition element, the biosensor being adapted to detect a target biological analyte present at a low concentration in bodily waste or on the wearer's skin.

Consequently, it is Applicants' position that the rejection of 1-11, 15-35 and 40-48 under 35 U.S.C. 102(b) as being anticipated by US 5,468,236 to Everhart et al. was improper.

Rejection Under 35 USC §103(a)

Claims 36-39 and 49-52 have been rejected under 35 USC §103(a) as being unpatentable over Everhart et al. '236.

Page 10 of 12

Claims 12-14 have been rejected under 35 USC §103(a) as being unpatentable over Everhart et al. '236 in view of Al-Sabah '723.

At the outset, Applicants submit that claims 12-14 and 36-39 depend directly or independent claim 1 and claims 49-52 depend on independent claim 40.

Applicant submits that since the rejection of claims 1 and 40 under 35 U.S.C. § 102(b) was improper, the Office has the burden to make a proper *pima facie* case of obviousness for these claims before it can allege that claims 4 and 5-8 are unpatentable under 35 U.S.C. § 103(a).

In addition, Applicants submit that it is basic patent law that "[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation ... to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure." In re Vaeck, 947 F.2d 488, USPQ 2d 1438 (Fed Cir. 1991). (emphasis added)

When considering the claimed invention as a whole, the Office must take into consideration the features of a biosensor disposed on the disposable article, the biosensor including at least one bio-recognition element wherein the biosensor is adapted to detect a target biological analyte present at a low concentration in bodily waste, features that are neither taught nor suggested by Everhart '236 or Al-Sabah '723.

Conclusion

In view of the previous amendments and remarks, it is submitted that all the claims are in condition for allowance. Early and favorable action on all claims is therefore respectfully requested.

If the next action is other than to allow the claims, the favor of a telephonic interview is requested with the undersigned representative.

Respectfully submitted,

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Page 11 of 12

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